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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHEN, STACY BROWN	
ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
12/04/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTOMail@traskbritt.com

Office Action Summary	Application No.	Applicant(s)	
	10/081,953	HENNEN ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-22* is/are rejected.

7)☒ Claim(s) *23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/8/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks filed on October 8, 2009 has been entered. Claims 1-16 and 18-23 are pending and under examination.

Claims Summary

2. The claims are drawn to a method for inducing a T-cell mediated immune response in an animal by administering an extract of an egg, wherein the egg extract consists of water soluble proteins of a yolk of an egg having molecular weights of about 8,000 Da or less; transfer factor is present in the extract, as are other egg yolk proteins having the specified MW. The transfer factor is present in a concentration greater than that present in the egg.

Response to Amendment

3. The following rejections are withdrawn:

The rejection of claims 1-3, 7-13, 15, 16, and 18-23 under 35 U.S.C. 102(b) as anticipated by Lee (US Patent 5,367,054), evidenced by Kirkpatrick *et al.* (US Patent 5,470,835) is withdrawn in view of Applicant's amendment.

The rejection of claims 4-6 under 35 U.S.C. 103(a) as obvious over Lee, evidenced by Kirkpatrick *et al.* (US Patent 5,470,835), as applied to claim 1, and further in view of Taylor (US Patent 5,001,225), is withdrawn in view of Applicant's amendment.

The rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Lee (5,367,054), evidenced by Kirkpatrick et al. (US Patent 5,470,835), as applied to claim 1, and further in view Dekich (*Poultry Science*, 1998, 77:1176-1180), is withdrawn in view of Applicant's amendment.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 and 18-22 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dopson (PGPub 2002/0044942A1, "Dopson", published April 18, 2002, with priority to provisional application 60/233,400, filed September 18, 2000), for reasons of record. Applicant indicates in the response filed October 8, 2009, that an affidavit may be filed once all other issues in this application are resolved.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokoro (US Patent 5,080,895) in view of Kirkpatrick *et al.* (US Patent 5,840,700, "Kirkpatrick"). The Tokoro patent has been used extensively in the prosecution of this application, being applied in rejections that have been reinstated and withdrawn several times. However, this rejection is

set forth upon re-consideration of the teachings of the Tokoro reference. Any inconvenience is regretted.

Tokoro discloses the administration of two types of compositions to treat or prevent disease in animals. The first type of composition comprises specific antibodies directed to various pathogens, produced by immunizing hens with antigens/pathogens and collecting eggs from the hens. The antibodies from the eggs are then isolated and formulated for administration to animals. The Office recognizes that this composition (the antibody composition) is primarily intended by Tokoro to be used to treat/prevent intestinal disease caused by certain types of pathogens that are not known to induce T-cell-mediated immunity. So, *this rejection is not based on the antibody composition described by Tokoro.*

Notably, the second type of composition described in the patent comprises an antibody-like factor, also called transfer-factor like component, produced by immunizing hens with antigens/pathogens and collecting eggs from the hens. The transfer factor-like component is then purified from molecules of greater than 10 kD. The term "antibody like factor" is found in col. 3, lines 18-26, and the term "transfer factor-like component" is found in col. 3, lines 30-35. It appears clear from the disclosure that the antibody-like factor and the transfer factor-like component are referring to the same molecule. Tokoro's composition comprising the transfer factor-like component is antibody-free, and contains molecules having a molecular weight of less than 10 kD (col. 5, lines 14-21). Thus, Tokoro recognizes that a) the transfer factor-like component is not an antibody, 2) that is has a lower molecular weight than antibodies, and 3) it is specific for the antigen used to immunize the hen from which the transfer factor-like component was produced. Tokoro suggests the use of virtually any antigen of choice for the production of a

substance containing transfer factor-like component, including those other than intestinal infectious diseases (col. 4, lines 16-18). Antigens from pollen, bacteria, viruses, molds, allergens, blood from affected animals, sperm and toxins may be used in the production of transfer factor-like component (col. 4, lines 53-57). Therefore, given Tokoro's characterization of the transfer factor-like component, which matches Applicant's description of "transfer factor" (*i.e.*, transfer factors are structurally analogous to antibodies but smaller than 10 kD, see paragraphs [0010] and [0013] of the instant specification), it is expected that Tokoro's composition contains antigen-specific transfer factor.

In previous arguments presented by Applicant, the question of whether transfer factor is actually produced in Tokoro's examples has been raised. Applicant has asserted that the antigen used by Tokoro, an ETEC antigen, is not expected to induce T-cell mediated immunity in hens, thus, the transfer factor-like composition produced by Tokoro in Example II is not expected to contain Applicant's transfer factor.

In light of that line of reasoning, the obviousness rejection relies on Tokoro's description of a transfer factor-like component that is specific for an antigen from a pathogen, in combination with a reference that teaches an antigen/pathogen that is known to induce T-cell mediated immunity in an animal. For example, Tokoro fails to disclose EBV-specific transfer factor. However, Tokoro suggests the use of virtually any antigen of choice for the production of a substance containing transfer factor-like component, including those other than intestinal infectious diseases (col. 4, lines 16-18). Antigens from pollen, bacteria, viruses, molds, allergens, blood from affected animals, sperm and toxins may be used in the production of transfer factor-like component (col. 4, lines 53-57). One would have been motivated to select an

antigen from a clinically significant pathogen such as Epstein-Barr virus, a known pathogen for which a vaccine is desirable to prevent mononucleosis (Kirkpatrick, col. 5, lines 7-30). One would have had a reasonable expectation of success that immunization of Tokoro's hens with EBV, or an antigen of EBV would have produced a composition comprising transfer factor-like component that is specific for EBV, given that the method of production is encompassed by the instant invention. The composition comprising transfer factor-like component is expected to contain Applicant's transfer factor because the composition is antibody-free, and has molecules with a molecular weight of less than 10 kD.

Another argument that Applicant has presented in previous remarks, is that Tokoro's method of purification of transfer factor-like component in Example II would not be expected to effectively purify Applicant's transfer factor because of the type of filter employed. The Office will address that issue here: Tokoro's method of purification is not presented as the only means of purification, rather, it is an example. (Note that there is no evidence of record to show that the use of a 0.45 micron filter would not be able to purify transfer factor to the degree instantly claimed.) Significantly, what Tokoro does teach is that transfer factor-like component is less than 10 kD. One of ordinary skill in the art would have had several purification methods from which to choose to purify transfer factor-like component. As long as the resulting composition comprises molecules of less than 10 kD, transfer factor-like component, and Applicant's transfer factor, are expected to be present in the resulting composition.

The Office notes that the claims recite, "water soluble proteins of a yolk of an egg having molecular weights of about 8,000 Da or less", and "transfer factor molecules having molecular weights of about 4,000 Da to about 5,000 Da". Tokoro's disclosure of a transfer factor-like

component that is not more than 10 kD, is reasonably within the metes and bounds of "about 8,000 Da or less". With regard to the range of "about 4 to 5 kD", this is merely a characterization of transfer factor's molecular weight; it is not limiting the extract to only those molecules that are about 4 to 5 kD and excluding those molecules that are greater than 5 kD. Regardless, it would have been obvious to purify Tokoro's transfer factor-like component to even lower molecular weights than 10 kD. Kirkpatrick teaches that transfer factors are smaller than antibodies, they do not transfer antibody mediated responses, and they do not induce antibody production (see Kirkpatrick, col. 1, lines 63-57). The molecular weight of transfer factor, according to Kirkpatrick, is in the range of 4 to 6 kD (see col. 3, first full paragraph, and col. 4, second full paragraph). Although Tokoro calls the molecules "transfer factor-like component", and Kirkpatrick calls the molecules, "transfer factor", one of ordinary skill in the art would readily recognize that these two molecules are the same based on their structure (both Tokoro and Kirkpatrick recognize that the molecules are not antibodies, but smaller), molecular weight (both Tokoro and Kirkpatrick recognize that the molecular weight is less than 10 kD), and function (both Tokoro and Kirkpatrick recognize that the molecules do not function as antibodies, but transfer/mediate cell-mediated immunity, see Kirkpatrick, col. 1, lines 49-62, and Tokoro, col. 4, lines 11-15).

As to the methods of administration of transfer factor, Kirkpatrick teaches that transfer factor can be administered intravenously, intramuscularly, subcutaneously or orally (see Kirkpatrick, col. 6, lines 56-61). Although neither Tokoro or Kirkpatrick suggest nasal or topical administration of transfer factor, it would have been obvious to use these routes depending on the patient and the disease being treated (*e.g.*, skin conditions may require topical administration). It

would have been well within the ability of the ordinary artisan to determine a route of administration that would be most beneficial or conducive to a patient depending on their condition.

Therefore, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

6. This action is made non-final in view of the new grounds of rejection set forth above. No claim is allowed. Claim 23 is objected to as being dependent on a rejected claim.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Stacy B. Chen/
Primary Examiner, TC1600